

**DRAINAGE SYSTEM****CROSS-REFERENCE TO RELATED APPLICATIONS**

[0001] This application claims benefit of and priority to U.S. Ser. No. 60/619,304, filed on Oct. 15, 2004 which is incorporated herein by reference in its entirety for all purposes.

**STATEMENT AS TO RIGHTS TO INVENTIONS MADE UNDER FEDERALLY SPONSORED RESEARCH AND DEVELOPMENT**

[0002] [Not Applicable]

**FIELD OF THE INVENTION**

[0003] This invention pertains to medical drainage devices.

**BACKGROUND OF THE INVENTION**

[0004] A urinary drainage catheter, such as the Foley catheter, is a hollow, tubular device commonly used in the medical profession for insertion into a patient's bladder via the urethral tract to permit the drainage of urine. Use of a urinary catheter is often necessary for patients that are undergoing surgery, orthopedically incapacitated, incontinent, or incapable of voluntary urination. An unfortunate problem with catheterization, however, is the development of sepsis and/or urinary tract infections (UTIs) as a result of bacterial invasion in the bladder and urinary tract by various microorganisms. Sepsis is potentially lethal and most prevalent in the elderly, where urinary tract and bladder infections become systemic very easily, especially if hygiene is poor and hydration of tissue is deficient. The risk of sepsis increases with the employment of urinary drainage catheters, where normal flora, and/or bacteria from feces or skin easily ascend into the bladder around the inserted catheter.

[0005] In addition, residual urine in stasis around the retention balloon provides a culture medium at warm body temperatures that facilitates the growth of bacteria. Consequently, bacteria are able to accumulate, multiply and become pathogenic in the bladder, eventually circulating into the kidneys and throughout the system, resulting in sepsis of the system. Because of this propensity to produce infection in the patient, medical practitioners often refuse to extend the use of catheters, despite their usefulness.

[0006] Urinary tract infections (UTIs) are the most common nosocomial infection, and greater than 90% of these are catheter related (Nicolle (2001) *Infections in Medicine*, 18: 153; Sedor and Mulholland (1999) *Urol Clin North Am*, 26: 821). Nosocomial UTIs are a source of increased morbidity, mortality, and increasing financial burden of healthcare systems worldwide, accounting for more than 1 million cases in U.S. hospitals annually (Foxman (2003) *Dis Mon*, 49: 53; Biering-Sorensen et al. (2001) *Drugs*, 61: 1275). Each episode of symptomatic nosocomial UTI adds nearly \$700-1,500 dollars to the hospital bill (Saint (2000) *Am J Infect Control*, 28: 68), and an annual cost to the US healthcare system of nearly \$451 million dollars (Jarvis (1996) *Infect Control Hosp Epidemiol*, 17: 552). Catheter-related bacteremia is estimated to cost nearly \$2,900 per episode (Id.). Subpopulations at greatest risk for nosocomial

catheter related UTI (the elderly, paraplegics, infants, pregnant women, diabetics, and patients with HIV/AIDS) (Id.).

[0007] The risk of UTI increases with increasing duration of catheterization. Recurrent infections lead to bacterial resistance to antibiotics. Long term catheterization has been associated with severe complications such as pyelonephritis (Warren (2001) *Int J Antimicrob Agents*, 17: 299; Huang et al. (2004) *Infect Control Hosp Epidemiol*, 25: 974), nephrolithiasis, epididymitis and prostatitis (Warren et al. (1994) *J Am Geriatr Soc*, 42: 1286). Bacteremia can occur when large static urine volumes and infection are combined with local urothelial trauma from chronic factors such as: catheter erosion, focal bladder wall ischemia due to persistent increased intraluminal pressures, and acute trauma from excessive catheter traction (Seiler and Stahelin (1988) *Geriatrics*, 43: 43). The discomfort associated with a distended bladder can cause unsupervised patients to pull their catheters out, resulting in urethral trauma/stricture, bleeding, and bacteremia.

[0008] Despite increasing numbers of patients with chronic indwelling Foley catheters, product innovation in this field has been limited to classes of material coatings designed to impede bacterial migration over the catheter and into the patient. Such new products have naturally focused on the urethral catheter component of the drainage system. For example, less reactive catheter materials such as silicone (Graiver et al. (1993) *Biomaterials*, 14: 465), low friction coatings such as Teflon, BN-74, and Hydrogel, and drug-eluting and silver impregnated surface coatings (Graiver et al. (1993) *Biomaterials*, 14: 465; Klarskov et al. (1986) *Acta Obstet Gynecol Scand*, 65: 295; Sabbuba et al. (2002) *BJU Int*, 89: 55; Gaonkar et al. (2003) *Infect Control Hosp Epidemiol*, 24: 506) were developed to decrease catheter-associated UTIs. These products have demonstrated inconclusive efficacy and unfavorable cost-effective value for even short-term prevention of urinary tract infections. No practical advances in product design have been made to improve long-term urinary catheter-related tract infection rates.

[0009] While bacteriostatic/bacteriosidal materials coatings active at the level of the catheter make intuitive sense to help prevent nosocomial UTIs, but such measures are ineffectual when persistent residual volumes of urine within the bladder serve as a medium for bacteria and source of infection.

[0010] Blockage is problem frequently reported by more than half of outpatients with chronic urinary catheters (Wilde (2003) *J Adv Nurs*, 43: 254; Kunin et al. (1987) *J Urol*, 138: 899). The literature suggests that the most common causes of catheter blockage include blood clots, sediment crystals and mucus within the catheter lumen (Getliffe (1994) *J Adv Nurs*, 20: 140). Catheter blockage accounts for many unscheduled office, evening and weekend visits, in addition to emergency room visits and visits by home nurses (Wilde (2002) *Home Healthc Nurse*, 20: 449). A study examining after-hours home care nursing calls notes that 22 of 25 patients reported catheter-related problems (Wilde (2003) *J Adv Nurs*, 43: 254).

**SUMMARY OF THE INVENTION**

[0011] In certain embodiments this invention provides systems for improved drainage from a bladder in a patient.